

**Remarks/Arguments**

Reconsideration of the above-identified application in view of the present amendment is respectfully requested.

Applicant respectfully thanks the Examiner for the telephone interview on November 19, 2008 during which, as noted in the Examiner's reply dated November 28, 2008:

Applicant explained the relationship of Factor B to the complement cascade. Applicant is considering amending the claim to recite that the antibody of the method possesses all of the properties recited in the claim, rather than reciting the properties in an alternative fashion. Applicant also explained that the recitation in the claim of "does not decrease factor B levels in the blood" is inherent in the earlier recitation in the claim of "preventing the formation of Bb" because the two events are intimately related. The examiner agreed that the amendment would differentiate the claimed invention from the prior art, which does not teach all of those limitations, and would address the new matter rejection.

By the present amendment, Applicant has amended claims 25 and 40 to recite that the anti-factor B antibody possesses all of the properties recited in the claim. Specifically, the antibody in an in vitro assay prevents factor B binding to C3b and properdin-bound C3b; prevents the formation of Bb; reduces C3a, C5a, and C5b-9 generation; reduces C3 conversion into C3a and C3b; reduces C5 conversion into C5a and C5b; reduces the activation of neutrophils, monocytes and platelets; and inactivates cells bearing C3a and C5a receptors.

Additionally, Applicant has cancelled claim 45 as the limitations of claim 45 were incorporated in claim 25 by amending claim 25 to recite that the antibody possesses all of the properties recited in the claim.

Below is a discussion of the 35 USC 112 rejection of claims 25-37 and 39-45.

Claims 25-37 and 39-45 were rejected under 35 USC 112, first paragraph, as failing to comply with the written description requirement. The Office Action argues that the limitation added to claims 25, 33, and 40 that recites "wherein administration of the antibody does not decrease factor B levels in the blood" is new matter because the cited examples are all in vitro assays, which do not include all the elements for the removal of immune complexes found in an in vivo environment, as is claimed, and there is no indication in any of the assays that reduction of factor B as a result of addition of anti-factor B antibody was measured, considered, or even pertinent to the assay.

Claims 25, 33, and 40 meet the written description requirement because the limitation "wherein administration of the antibody does not decrease factor B levels in the blood" is inherent in the earlier recitation in the claims of "preventing the formation of Bb". As discussed in the teleconference with the Examiner, during complement activation, the formation of Bb is intimately related to the factor B levels in the blood. In order for Bb to be generated in the blood, factor B must first complex C3b to form a C3bB complex. The factor B of the C3bB complex is then cleaved by factor D to form Bb and Ba. Thus, factor Bb is formed from factor B, and upon complement activation, factor B levels in the blood cannot decrease unless factor B is

cleaved to form factor Bb. Therefore, an anti-factor B antibody that prevents the formation Bb would implicitly and inherently not decrease factor B levels in the blood.

Accordingly, Applicant respectfully requests that the 35 USC 112, first paragraph, rejection of claims 25, 33, and 40 be withdrawn because the limitation of "does not decrease factor B levels in the blood" is inherent in the earlier recitation in the claims of "preventing the formation of Bb

Claims 26-27 and 29-34, 36-37, 39, and 41-44 depend either directly or indirectly from claims 25, 33, and 40 are allowable because of the aforementioned arguments with respect to claims 25, 33, and 40.

In view of the foregoing, it is respectfully submitted that the above-identified application is in condition for allowance, and allowance of the above-identified application is respectfully requested.

Please charge any deficiency or credit any overpayment in the fees for this amendment to our Deposit Account No. 20-0090.

Respectfully submitted,

/Richard A. Sutkus/  
Richard A. Sutkus  
Reg. No. 43,941

TAROLLI, SUNDHEIM, COVELL,  
& TUMMINO L.L.P.  
1300 East Ninth Street, Suite 1700  
Cleveland, Ohio 44114  
Phone:(216) 621-2234  
Fax: (216) 621-4072  
Customer No.: 26,294